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| 09/911,218 | 07/23/2001 | Yongxing Qiu | CL/V-31563P1 | 4902 |

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THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER

MICHENER, JENNIFER KOLB

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1762

DATE MAILED: 06/13/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/911,218

Applicant(s)

QIU ET AL.

Examiner

Jennifer Kolb Michener

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-- Th MAILING DATE of this communication app ars on th cov r sh et with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Specification

1. The new matter objection to amendment B filed 8/7/2002 under 35 U.S.C. 132 has been withdrawn in light of Applicant's amendments C and D and thorough remarks.

The following new objection is made based on Applicant's amendment D:

2. To obviate the new matter objection, Applicant removed formulas (5), (6), and (5a) from the specification. In so doing, reference to characters named within those formulas remains in the specification. For example, the phrase "wherein L is C₂-C₆-alkyl" remains in the specification to define "L" of formula (5), even though L is no longer present in a formula. This is not clear.

Information Disclosure Statement

3. The information disclosure statement filed 4/14/2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Journal documents AC and AD have not been supplied by Applicant.

The IDS has been placed in the application file, but these documents have not been considered.

Examiner's Suggestions

4. In claims 4 and 5, for clarity, Examiner suggests the use of commas after the words "wherein" and "depositing".

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-13 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Examiner maintains the rejection.

Specifically, Applicant's amendment B requires the polyelectrolytic tie layer to be composed of at least a "polyionic material which is not covalently attached to the surface of the article". As outlined in the previous office action, there does not appear to be support for this limitation in the originally-filed disclosure. Examiner notes that on page 45, Applicant states that the polyelectrolytic tie layer is "adsorbed onto and/or heteropolarly bound on the surface". While these types of interaction may not be covalent in nature, this teaching on page 45 does not provide support for the broad limitation of "not covalently attached" required by Applicant's amendment.

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-2, 5-6, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (U.S. Pat. 5,409,731).

Examiner maintains the rejection.

9. The rejection of claims 1-2, 5-6, and 12-13 under 35 U.S.C. 102(b) as being anticipated by Wilson (U.S. Pat. 6,050,980) have been withdrawn in light of Applicant's amendments C and D.

The following new rejection is made:

10. Claims 1, 3-9, 12, 13, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheu et al. (5,807,636).

Sheu et al. teaches a method of modifying the surface of an article to improve wettability comprising depositing a polyelectrolytic layer on the surface of the article, ionically bound thereto (abstract; col. 1, line 11; col. 2, lines 18 and 65; throughout). The ionic bonds meet Applicant's limitation of "not covalent". The charges along the polymer backbone of the polyelectrolytic layer form "reactive sites" as required by Applicant. After coating with this polyelectrolytic layer, one or more additional polyelectrolytic layers may be coated thereon, with alternating charges (col. 7, line 32 and line 37). The

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opposite charges of the first and subsequent layer will interact, thus grafting the subsequent layer to the first layer via "reactive sites". The first layer acts as a tie coat to the subsequent layer. The subsequent layer acts as the "active agent", as required by Applicant.

Examiner notes that Sheu teaches the use of an ionic polymer layer prior to the first polyelectrolytic layer (abstract), however the comprising language of instant claim 1 does not exclude such a layer or the use of additional coating steps. Furthermore, once coated with this ionic polymer layer, the article surface would merely become the coated surface. Lastly, some of the Examples do not require the use of the ionic polymer layer when the substrate is already polymeric (col. 4, line 33; at least Examples 1-2).

Regarding claim 2, it is Examiner's position that the interaction between the two polyelectrolyte layers, acting as Applicant's tie layer and active agent, which comprise polymer chains containing hydrogen and ionic groups, will inherently involve hydrogen bonding.

The final layer of Sheu acts as the "active agent" of claim 1. Regarding claim 3, which further requires the active agent to be a polymer, the final layer of Sheu is a polymer (col. 7, lines 33), as Sheu teaches it to be one of the additional polyelectrolyte layers.

In regard to claims 4 and 5, Sheu teaches, as outlined above, the deposition of a polyelectrolyte layer, followed by one or more additional polyelectrolyte layers. When

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only one additional, subsequent layer is used as the "active agent", the limitation of claim 5 is met. When there are "more", the limitation of claim 4 is met. The layers may be applied successively.

As required by claim 6, solutions are used for deposition in Sheu (col. 7, line 50).

Regarding claim 7, Sheu teaches dipping for use in applying the successive layers with opposite charges (col. 7, line 31). Alternatively, a single solution can be used by Sheu for the polyelectrolyte layers (col. 7, line 45), as required by claim 8. Other methods of application taught by Sheu include spraying, as required by claim 9.

Regarding claims 12 and 13, Sheu teaches the use of such modification on a contact lens (examples), a biomedical device.

Regarding claim 17, Sheu specifically teaches that the first tie layer may be applied by spraying the polyelectrolyte layer (col. 7, line 21), followed by dip coating a second polyelectrolyte layer of opposite charges (col. 7, line 31 and line 38).

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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12. The rejection of claims 1-6 and 12-13 under 35 U.S.C. 103(a) as being unpatentable over Takemura et al. has been withdrawn in light of Applicant's amendments C and D.

13. The rejection of claims 1-4, 6-13 and 17 under 35 U.S.C. 103(a) as being unpatentable over Vanderlaan et al. has been withdrawn in light of amendments C and D.

The following new rejection is made:

14. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheu.

Sheu teaches that which is disclosed above, including the use of dipping or spraying the first polyelectrolyte layer and dipping the second. Sheu fails to specifically teach that the subsequent layer may also be formed by spraying, as required by claim 10.

Since Sheu teaches the interchangeability of dipping and spraying for applying the first layer, it would have been obvious to one of ordinary skill in the art, using the teachings of Sheu, that the second layer could be sprayed, rather than dipped, with the expectation of similar, successful results since Sheu teaches the appropriateness of spraying versus dipping when applying charged polyelectrolyte coatings.

Claim 11 then requires that the coatings be applied together, instead of successively, by spraying. As outlined above in the 102 rejection, Sheu envisions the use of one coating solution containing more than one polyelectrolyte coating for the dipping operation. For

those reasons outlined immediately above, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to apply the polyelectrolyte materials together in one spraying operation, just as was taught in the dipping operation with the expectation of similar results because dipping and spraying are taught to be interchangeable for coating polyelectrolytes.

Response to Arguments

15. Applicant's arguments filed 4/14/2003 regarding Nakagawa et al. and the new matter rejection have been fully considered but they are not persuasive.

Applicant argues that Nakagawa fails to teach non-covalent attachment of the tie layer to the surface because while the tie layer is "adsorbed", the reference teaches "then... is contacted with a solution containing a crosslinking agent to crosslink (i.e., covalently attach) the ...polymer on the... surface".

Examiner disagrees.

The teaching of crosslinking a polymer is not synonymous to covalent attachment of such a polymer to a substrate. The polymer coating may be crosslinked with itself using the crosslinking agent with no involvement of the substrate in said reaction.

Furthermore, Applicant's characterization of the reference to require adsorption, then cross-linking to negate the taught non-covalent adsorption ignores the other embodiment of Nakagawa. Nakagawa also teaches an embodiment method wherein "the adsorption and the crosslinking reaction are conducted at once", simultaneously. If crosslinking inherently required covalent bonding to the substrate, as Applicant argues,

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then Nakagawa would be unable to adsorb (i.e., not covalently attach) the polymer coating at the same time as cross-link the coating. Therefore, no covalent bond occurs in Nakagawa.

Applicant provides numerous arguments against the new matter rejection outlined above.

In response to Applicant's argument in Amendment C that the substrate of Applicant does not contain any appropriate reactive groups prior to coating to allow covalent bonds, Examiner notes that the lack of appropriate groups prior to coating does not provide basis for the limitation excluding covalent attachment at any time in Applicant's method. There remains no basis for the broad limitation "not covalently attached" in claim 1.

In response to Applicant's argument in Amendment C that certain examples of Applicant teach dipping (i.e., physical deposition) without crosslinking agents, Examiner notes that these teachings are merely exemplary. Furthermore, Examiner disagrees that "dipping" constitutes "physically depositing", to the exclusion of covalent bonds.

In response to Applicant's argument in Amendment C that the incorporated 20010045676 reference must not use covalent attachment because the article can be transferred from a mold surface to the contact lens, Examiner disagrees. Covalent bonding does not exclude such a transfer. Furthermore, this transferring operation appears irrelevant to the coating operation of the instant claims.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rubner et al. (5,518,767) is cited for teaching alternating polyionic layers attached to a substrate via electrostatic bonds. Wang et al. (6,011,082) is cited for teaching surface modification of contact lenses with polyionic chemicals attached to the substrate non-chemically for subsequent attachment of active agents, such as heparin (see Figure 2). Ellis et al. (4,168,112) is cited for teaching electrostatic attachment of a polyelectrolyte to a contact lens.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

A handwritten signature in cursive script, appearing to read "J Kolb Michener".

Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
June 10, 2003